

REMARKS

I. The Subject Matter of the Claims

The subject matter of the claims relates generally to methods of generating specific nucleic acids of greater lengths than a typical SAGE tag, providing a material that is amenable to further characterization and thereby facilitating resolution of multiple SAGE tag identifications as well as assignment of orphan SAGE tags to genes.

II. The Amendments

Applicants would first like to thank the Examiner for the telephonic interview on January 27, 2004, during which the instant amendments were discussed. Applicants herein confirm the cancellation of claims 21-41 and reserve the right to pursue such subject matter in continuing applications. The claims generally have been amended to address 35 U.S.C. §112, second paragraph, matters of form and clarity. As amended, the claims clarify the nature of the claimed subject matter without narrowing the scope thereof.

III. Patentability Arguments

A. The Rejection of Claims 1-15 and 18-20 under 35 U.S.C. § 103(a) Should Be Withdrawn

The Examiner rejected claims 1-3, 5-9, 11-12, and 15 under 35 U.S.C. § 103(a) over van den Berg *et al.* in view of Liang *et al.*, Nucl. Acids Res. 22:5763-5764 (1994). Claim 4 was rejected under § 103(a) over van den Berg *et al.*, in view of Liang *et al.* and Lundberg *et al.*, Gene 108:1-6 (1991). Claim 10 was rejected under § 103(a) over van den Berg *et al.*, in view of Liang *et al.*, and Spinella (U.S. Pat. No. 6,461,814). Finally, claims 13, 14, and 18-20 were rejected under § 103(a) over van den Berg *et al.*, in view of Liang *et al.*, and Velculescu *et al.*, Science 270:484-487 (1995).

In support of the rejection, the Examiner maintains the arguments presented in the previous Office action (mailed on March 26, 2003) and asserts that the Declaration of San Ming Wang (filed on August 26, 2003 in response to the aforementioned Office action of March 26, 2003) was ineffective in that only one (Dr. Wang) of the joint inventors executed the declaration under 37 C.F.R. § 1.131.

In response, Applicants first note that the van den Berg *et al.* reference was apparently accepted for publication on July 19, 1999 and was published in September, 1999. The instant application claims the priority benefit of provisional U.S. Patent Application No. 60/173,617, which was filed on December 29, 1999. Accordingly, van den Berg *et al.* is potentially available as a reference only under 35 U.S.C. § 102(a).

Attached hereto as Appendix A is a Declaration of San Ming Wang, Jian-jun Chen, and Janet Rowley Under 37 C.F.R. § 1.131, which was signed by the inventors on February 17, 2004, and February 18, 2004, and was filed with the U.S. Patent and Trademark Office as Appendix A with Applicant's Reply Under 37 C.F.R. § 1.116 on February 19, 2004. San Ming Wang, Jian-jun Chen, and Janet Rowley are the joint inventors named on the instant application. In the Declaration, each of the joint inventors asserts that the invention of the pending claims was completed prior in time to July 19, 1999, and, thus, prior to the earliest possible publication date of van den Berg *et al.*; including the apparent publication date of September, 1999. To corroborate those assertions, relevant pages of San Ming Wang's laboratory notebook are attached as Exhibit A to that declaration. The Declaration establishes that the named inventors of the instant application had completed the claimed invention prior in time to the publication of van den Berg *et al.* Accordingly, the attached declaration, signed by all of the inventors of the claimed subject matter, effectively removes van den Berg *et al.* as a reference available against any claim pending in the instant application.

With van den Berg *et al.* unavailable as a reference against the pending claims, the Applicants submit that a *prima facie* case of obviousness under 35 U.S.C. § 103(a) of any pending claim cannot be established. More particularly, there is no support for the assertion that any of the following claim elements were known in the art: a method of serial analysis of gene expression that utilizes a tag-specific primer and an anchored poly(dT) primer; that the products of such methods may be used to either identify gene-specific sequence information, to isolate a full-length cDNA clone, or to analyze tissue-specific gene expression; or that such methods may be improved by adjusting PCR conditions, including MgCl₂ concentration. None of the cited secondary references (Liang *et al.*, Lundberg *et al.*, Spinella, or Velculescu *et al.*) discloses any of these features, and the Examiner has not asserted that they do. Accordingly, the Applicants submit that a *prima facie* case of obviousness for any one of claims 1-15 and 18-20 under 35 U.S.C. § 103(a) over any combination of the cited references has not been established and the rejection should be withdrawn.

B. The Rejection of Claims 1-20 under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn

Claims 1-20 were rejected by the Examiner for the recitation of the phrase "single-base anchored primer" in claims 1 and 7-9. The Examiner asserts that the aforementioned phrase is not supported by the specification and, as such, constitutes new matter. In response, Applicants disagree and maintain that the specification does provide support for the challenged language because *ipsis verbis* support is not required by the statute. To clarify the claimed subject matter, however, Applicants have amended the claims by reintroducing the relevant phrase as recited in the original claims, i.e., "single-base anchored primer" with the phrase "single-base anchored oligo-dT primer." The amendments to the claims (present and previous) to clarify the language of the relevant preimer have not altered the scope of any claim.

By way of background, the pending claims have consistently been drawn to methods for characterizing SAGE tag fragments that comprise, in pertinent part, the use of a non-specific oligo-dT anti-sense primer for PCR-mediated amplification. To ensure consistent registration of this non-specific primer, a single terminal base that is not a dT base was included as an anchor to ensure that all oligo-dT primers would anneal at the same end of the relevant poly-A tract, regardless of the length of that poly-A tract. Accordingly, the claims originally recited a "single-base anchored oligo-dT primer." Applicants continue to maintain that one of ordinary skill in the art would understand the claim-recited term to have the unambiguous meaning described above.

To address a claim rejection under 35 U.S.C. § 112, second paragraph, Applicants amended the claims to recite a "single-base anchored primer" to clarify to all that the primer had a non-dT anchor base. See Amendment filed August 26, 2003. In the same Amendment, the Applicants clarified that the "base excluding dT" (i.e., the anchor base) was a "single" base. Claims 1 and 8-9 were similarly amended to remain consistent with claim 7 as amended. Applicants continue to assert that clarification of the claimed subject matter was unnecessary when properly viewed from the perspective of one of ordinary skill. To make that point clear, Applicants have amended the claims back to the original recitations of oligo dT primer.

In the instant amendment, Applicants have re-introduced the term "oligo dT" to claims 1 and 7-9. Applicant's submit that the addition of the term "oligo dT," which was present in the claims as originally filed, combined with the term "single," submitted in the amendment filed August 26, 2003, clarifies the claimed subject matter. Specifically, it will be apparent to one of ordinary skill in the art that the antisense primer, recited in the claims is an oligo-dT primer (claims 1, 8-9) that is anchored at the 3' end by a single base, that single base being anything other than dT (claim 7). For example, the single base at the 3' end of the primer can be either dA, dG, or dC. This is explicitly taught in the application as filed (see, e.g., page 9, line 26).

For the foregoing reasons, Applicants submit that the rejection of claims 1-20 under 35 U.S.C. § 112, second paragraph, for asserted indefiniteness has been overcome and should be withdrawn.

CONCLUSION

In view of the amendments and remarks made herein, Applicants submit that claims 1-20 are in condition for allowance and request notification of the same.

Respectfully submitted,
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